

OFFICE OF ACQUISITIONS  
NATIONAL CANCER INSTITUTE

REQUEST FOR PROPOSAL NUMBER: N01CM01018-83

Amendment No.: 5

Date of Issuance: 09/10/2010

The above numbered Request For Proposal (RFP) is amended as set forth below. The hour and date specified for receipt of Offerors remains unchanged: \_\_\_\_\_.

Offerors MUST acknowledge receipt of the amendment prior to the hour and the date specified in the solicitation or as amended, by separate letter, telegram, or Electronic Mail which includes a reference to the RFP and Amendment number(s). For your convenience, the Proposal Intent Response Form is provided in SECTION J - List of Attachments of this RFP, for this purpose.

FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERORS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER.

This Amendment revises the RFP as stated below:

This section of the amendment provides responses to questions submitted by potential offerors.

Questions 1-29 and their responses were posted in Amendment No. 4 to the Solicitation on August 25th. The following questions and responses are continued from Amendment 4.

Question 30: How much focus should be placed on the Small and Disadvantaged Business Concerns? As you are aware, we have a consortium of several academic institutions where most of the expenses will occur. The predominant expenses in this program are salaries of faculty and staff employed at the consortium members (not small and disadvantaged businesses), and patient care related costs. Procurement of services outside of the consortium is anticipated to be quite small and insignificant. Each institution has independent policies addressing using small businesses that would guide purchasing of materials at each site. Is describing this process adequate to meet the requirements of this section? Is the Small Business Subcontracting Plan referenced required as part of the submission package?

Response: We have recently become aware that this acquisition has been determined exempt for the requirement of the Small Business Subcontracting Plan. Please disregard the requirements for a Small Business Subcontracting Plan stated in the Request for Proposal and discussed in the Preproposal Conference slides.

Question 31: The RFP isn't clear on where to place the Proposal Summary and Data Record form (NIH-2043). Is it to be included in the Technical or Business Proposal?

Response: In the Solicitation under Section J - Business Proposal Attachments - the Proposal Summary and Data Record is identified. Please submit as part of your Business Proposal.

Question 32: Assume PI is at the NIH cap in YR 01 of the budget. Can we increase his salary by 3% in each of the subsequent years? The spreadsheet automatically calculates an increase if you put in a 3% as the default increase.

Response: We cannot negotiate for costs above the legislated salary caps. If the proposal is submitted with salary costs above the legislated salary caps the amounts will be reduced during negotiations.

Question 33: Can we assume that in future years the capitation rates may rise? For example if Years 01 and 02 have a capitation rate of \$100/patient. For Years 03 & 4 can we propose a capitation rate of \$105/patient?

Please refer to the Power Point presentation used during the Preproposal Conference. The capitation rate and the basis for the rates being negotiated is discussed at length.

Question 34: In regards to the Subject Accrual, can you please clarify the base v options; how many subjects should we include in each year. It was unclear if we should use 171 in ALL years or 171 in YR 01 only and 135 in YR 02-05. We are formulating a budget and this is important to calculations.

Please adhere to the number of subjects identified in the RFP. No changes have been made to the number of subjects accrued. As discussed in the Preproposal Conference and in the Power Point slides, the number of subjects to be proposed is simply an estimate and the final amounts will be determined during negotiations.

Question 35: We will be providing copies of open and in-development full protocols as an appendix. Is it acceptable to provide these materials in electronic format on a CD only? Or do you prefer that we provide paper copies as well?

Response: Please do not submit copies of protocols. The reviewers do not have time to read them.

Question 36: The same question applies to other lengthy appendix materials that we'll be providing, such as manuscripts and floor plans. Could they be provided on a CD only?

Response: Hard copies of the floor plan must be submitted. There is no requirement in the RFP for the submission of manuscripts.

Question 37: Paragraph 4 of the Resources and Organizational Experience section within the Additional Technical Proposal Instructions states, "If the consortium does not already exist, describe the plans for rapidly structuring and initiating collaboration." Does this provision impact the Business Proposal section also? If the consortium does not exist then we would not be able to include costing details, letters of commitment, etc. for subcontractors until such time that the consortium was formed. Is that acceptable?

At such a time when the consortium is formed, would you then require the aforementioned documentation from each member of the consortium?

Response: Offerors should show how the prime and subcontractors will be able to form a functioning, integrated, and interactive clinical trials consortium in order to fulfill the requirements of the Statement of Work (SOW). The absence of a track record of successful performance between the proposed prime and subcontractors may be considered a weakness of the proposal.

As this is a competitive acquisition a proposal including the "Breakdown of Proposed Estimated Cost" is required to be submitted for each prime and subcontractor proposed to perform on the project.

Question 38: Does "activation of the study within 210 days of LOI submission," as indicated on page 10 of Attachment 7, Additional Technical Proposal Instructions, mean CTEP approval-on-hold status, as indicated on page 5 of Attachment 2, Statement of Work, where it says, "Timeline excludes contracting, drug supply, IRB, FDA?"

Response: The 210 days to protocol activation means that the study is open to enroll patients.

Question 39: Is the required SEPARATE SECTION of the Technical Proposal entitled, "HUMAN SUBJECTS" (page 42 of the original RFP) excluded from the page limitations as is standard practice?

Response: You may include your documentation concerning Human Subjects in the Appendix. Please clearly mark your Technical Proposal Table of Contents to indicate the location for this information.

Question 40: We have received many questions from some offerors concerning the spreadsheets entitled "Breakdown of Proposed Estimated Costs" that are required to be completed and submitted. We have to ask that you submit the spreadsheets as requested. If there are difficulties with the formulas, or the links between the sheets for Subject Accrual, Tissue Collection and Imaging to the Summary Page we will have to make those corrections as the budgets are received and evaluated. It is not possible to trouble shoot these spreadsheets remotely.

Question 41: The response to Question 29 indicates that for Subject Screening Costs, up to \$500 per subject screening for molecular abnormalities can be included in the proposal. The response instructed "each option for accrual will be accompanied with an option for Screening Assays, and offerors are to incorporate the cost in a separate line item in the Breakdown of Proposed Estimated Costs."

Are we to assume that there are 9 options annually for Subject Screening? How many subjects are allowed per options? How about base 36 patients? n option for Screening Assays, and offerors are to incorporate the cost in a separate line item in the Breakdown of Proposed Estimated Costs."

Response: For the Screening Assay Option please assume the same number of subjects that are currently identified for the Base and Option Quantities. Offerors will have to insert a row into the EXCEL spreadsheet (Breakdown of Proposed Estimated Costs) to include the estimates for this new budget item.

This section of the amendment provides responses to questions submitted by potential offerors.

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